

This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

**1 (Original).** A method for treating erythema nodosum leprosum using thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, said method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has received an approval code for the prescription from a computer readable storage medium, wherein generation of the prescription approval code comprises the following steps:

- a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;
- b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;
- c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;
- d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and
- e. upon a determination that the risk is acceptable, generating the prescription approval code to be received by the pharmacy before the prescription is filled.

**2 (Original).** A method according to claim 1 further comprising registering in the medium the physician who prescribed the drug.

**3 (Original).** A method according to claim 1 further comprising registering the pharmacy in the medium.

**4 (Original).** The method of claim 1 further comprising counseling the patient as to the risks of taking the drug and advising the patient as to risk avoidance measures, in response to the risk group assignment.

5 (Original). The method of claim 4 wherein the counseling comprises full disclosure of the risks.

6 (Original). The method of claim 5 wherein the prescription is filled only following the full disclosure and informed consent of the patient.

7 (Original). The method of claim 6 wherein the informed consent is registered in the computer readable storage medium prior to generation of the prescription approval code.

8 (Original). The method of claim 7 wherein the risk group assignment and the informed consent is transmitted to the computer readable storage medium by facsimile and interpreted by optical character recognition software.

9 (Original). The method of claim 1 further comprising:

- f. defining for each risk group a second set of information to be collected from the patient at periodic intervals;
- g. obtaining the second set of information from the patient; and
- h. entering the second set of information in the medium.

10 (Original). A method for treating a patient having a disease or condition which is responsive to thalidomide while restricting access to thalidomide for patients for whom thalidomide may be contraindicated, the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval comprising the following steps:

- a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;
- b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;

c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;

d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and

e. upon a determination that the risk is acceptable, generating the prescription approval before the prescription is filled.

11 (Original). A method according to claim 10 further comprising registering in the medium the physician who prescribed the drug.

12 (Original). A method according to claim 10 further comprising registering the pharmacy in the medium.

13 (Original). The method of claim 10 further comprising counseling the patient as to the risks of taking the drug and advising the patient as to risk avoidance measures, in response to the risk group assignment.

14 (Original). The method of claim 13 wherein the counseling comprises full disclosure of the risks.

15 (Original). The method of claim 14 wherein the prescription is filled only following the full disclosure and informed consent of the patient.

16 (Currently Amended). The method of claim 15 wherein the informed consent is registered in the computer readable storage medium prior to generation of the prescription approval ~~code~~.

17 (Original). The method of claim 16 wherein the risk group assignment and the informed consent is transmitted to the computer readable storage medium by facsimile and interpreted by optical character recognition software.

18 (Original). The method of claim 10 further comprising:

- f. defining for each risk group a second set of information to be collected from the patient at periodic intervals;
- g. obtaining the second set of information from the patient; and
- h. entering the second set of information in the medium.

19 (Original). A method for treating a disease with a drug known or suspected of having teratogenic properties while restricting access to the drug by patients for whom the drug may be contraindicated the method comprising permitting prescriptions for thalidomide to be filled by a pharmacy only after the pharmacy has become aware of approval of a prescription for thalidomide for the patient from a computer readable storage medium, the generation of the prescription approval comprising the following steps:

- a. defining a plurality of patient risk groups based upon a predefined set of risk parameters for thalidomide;
- b. defining a set of information to be obtained from the patient, which information is probative of the risk that an adverse side effect is likely to occur if thalidomide is taken by the patient;
- c. in response to the information set, assigning the patient to at least one of the risk groups and entering the patient, the information and the patient's risk group assignment into the medium;
- d. based upon the information and the risk group assignment, determining whether the risk that the adverse side effect is likely to occur is acceptable; and
- e. upon a determination that the risk is acceptable, generating the prescription approval before the prescription is filled.